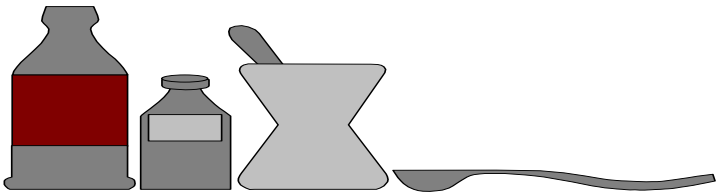

MEDI-CAL DRUG USE REVIEW BOARD

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FEBRUARY 2003 DUR Board Minutes

ROLL CALL AND GUESTS: Called to order. Board members in attendance: Dr Stahl, Dr Schell (phone conferencing), Dr Jones, J. McBride (phone conferencing), and Dr Wong. Absent: Dr McCart, Dr Albertson. Staff: Vic Walker, DHS; Laurie Squartsoff, DHS; Veronica Zepeda, DHS; Nandakumar Prabhakaran, EDS; Patrick Robinson EDS; Jacquie Granger EDS; Jude Simon-Leack EDS; Guests: Larry Dickey (DHS Protection of Human Subjects Committee); Dennis Long (Administrator, DHS Protection of Human Subjects Committee); Keli Griffiths, (Janssen Pharmaceutica); David Schestak (Johnson and Johnson), Dorothy Chan Ochida (Pharmacia); Wendy Fong (Abbott Laboratories); Gus Boesch (Biovair), Victor Torrence (Purdue), Richard Morita ((Pfizer), Rodger Powers (Bristol-Meyers), Welyn Bui (Eli Lilly); Trina Clark (Eli Lilly);

Priority Topic – HIPAA and Protection of Human Subjects – Vic Walker introduced Dr Larry Dickey and Dr Dennis Long of the Health and Human Services Protection of Human Subjects Committee to speak on the issues of HIPAA and protection of human subjects. This invitation is intended to help address some of the issues in the DUR Board's newer projects, including arthritis and asthma activities. Points made by Dr Long and Dr Dickey include:

a) Committee of the Protection of Human Subjects (CPHS) is undergoing process of reorganization and a more detailed explanation of policies and procedures will need to be deferred to a future meeting when these materials are finalized and made public.
b) CPHS is actually an Agency Committee, not one within a department, members being appointed and membership composed of people both within departments and from outside institutions. Meetings are every two months and the committee is supported by a full time administrator and other staff.
c) CPHS is an institutional review board (IRB) and has an agreement with the Federal Government and the Department of Health and Human Services, operating under what is referred to as the 'common rule', which addresses the question of what is research. 'Research' means the systematic investigation including research, development, testing and evaluation designed to develop or contribute to generalizable knowledge.
d) A key word in the above definition is generalizable knowledge. If the intention is to do a study and ultimately use the study outside of one's program operation, then it becomes research and

requires review and approval by an IRB. This includes anything that is intended for publication as well. It is always good to go to an IRB first if publication is an eventual goal because if you subsequently decide to publish and have NOT gone to an IRB, there may be some significant problems because IRBs are not supposed to approve research that was performed prior to their involvement.

e) The Atypical Antipsychotic Education Project (AAEP) is understood to be using Medi-Cal claims data only and thus is eligible for review via an expedited process. This means that one member of the committee and the committee chair can review this without waiting for the two-month cycle. Thus this kind of request can be processed in a month or less. (**Attachment One – checklist from CPHS).**
f) Submission of materials to CPHS includes a completed checklist and a protocol document approximately four pages in length.
g) HIPAA enters this picture because it is meant to target covered entities – Health care providers, a clearinghouse, and others that have personal health information. Medi-Cal is considered a covered entity but it is virtually impossible to go back and obtain informed consent/patient authorization from the participants. The only other option is to obtain a waiver of patient authorization, which is obtained through CPHS's normal review process.
h) Five specific issues HIPAA requires to be addressed which are the first five items on the checklist.

Questions and Answers Regarding This Topic:

Question One - Are physicians considered a 'subject' if their prescribing behavior is being reviewed and if so, must we obtain consent from them? And if we can't obtain it, can we apply for a waiver of physician authorization?

Answer One - HIPAA does not address physicians and their data. The common rule might cover them but this is hard to address without looking more closely at the program design. Assessment of prescribing would be considered a part of routine evaluation but if a statement about "x per cent of physicians prescribe this way" then a waiver might be helpful.

Question Two – Do we need this waiver if we intend to contact these same physicians and educate or otherwise encourage them to modify their prescribing behavior? If no waiver is needed, would the CPHS be willing to write a memo to this effect? If the same information regarding the physicians is published, is a waiver then necessary?

Answer Two – Physician contact becomes program evaluation or administration and not research. Therefore a waiver is NOT needed. The CPHS would be willing to write a memo to this effect but would need to know the individual activities intended. At a general level, the minutes of this meeting can state this provision. (Decision/Policy item). If the same information is published under the guise of performing the work of DUR, then it is not research and does not require a waive. If, however, the project starts out at its inception with the intent of research, then the waiver is necessary. It may be wise to submit a protocol for a project to CPHS because then the committee could return it to the submitters with the note that it is not research.

Dr Wong noted that research does not generally include behavioral discipline or modification whereas the DUR Board activities may very well include this. A separation between these two activities is important to maintain.

Question Three – If one's own institution has an IRB process, is it necessary to also submit to the Department of Health CPHS? What happens if two different IRBs generate conflicting direction?
Answer Three – If a project is considered a Department of Health Services activity, then it must be submitted to the CPHS for an IRB even if it is also required by the institution at which the project is operating. Differences between IRBs are rare but when it occurs, they usually find common ground.

Question Four – If a project is simply looking at records, including clinical documentation, is it still eligible for an expedited review?
Answer Four- If there is no contact with the patient, an expedited review is likely but any contact with the patient, such as through surveys or mail or email, then a regular review is necessary. In the case of a very benign survey (low degree of risk or confidentiality of data collected) or a very simple one, an expedited review is possible and the Board may require an information sheet (no signature or return acknowledgment required) to accompany the survey.

Question Five – If a study were to be performed, does de-identification need to be perform on the claims data? If data is being provided to a DUR Board member, what then?
Answer Five - It is preferred that Medi-Cal performs the de-identification but it is not necessary if certain restrictions are observed. The break point is whether the State is providing the information to the DUR Board members for the purpose of program administration or research. CalOHI (Office of HIPAA Implementation) is the resource for resolving some of this. There are certain user agreements that must be set up if data exchange under HIPAA is going to occur. Still, if a statute is in place that enables a group to do this kind of work, the statute overrides these restrictions.
Additional information on this topic will be available soon on a website and a conference call or other type of interactive contact can be arranged in the future, depending on the DUR Board's needs. END of TOPIC.

Approval of Minutes: Janeen McBride moved to accept the minutes of the November 2002 DUR Board Meeting as presented. Dr Wong seconded the motion. Discussion included Dr Wong's commendation of Jude Simon-Leack related to the excellent preparation of the minutes and related clinical materials provided. He felt these materials were very useful and beneficial to the DUR Board process. All voted in favor, no abstentions. The DUR Board Minutes of November 2002 are approved as submitted.

Operational Issues: Vic Walker noted that there is one vacancy remaining to be filled for the DUR Board and it is for a pharmacist. He is reviewing a number of applications at this time. Kevin Gorospe stated that the current telephone conferencing format of the DUR Board meeting with Board members participating in a meeting by phone as well as voting by phone is in compliance with requirements of the Brown Act to the best of his knowledge. The Board will act with the presumption of compliance and the legitimacy of telephone participation and continue to do so unless otherwise notified.

New Business:

a) Annual Report – Jude is waiting for the final Annual Report format to be announced by CMS before starting on the report preparation. CMS has not announced the final report format pending a review of the format by the Office of Management and Budget (OMB).
b) Biannual review of bulletin effectiveness – topic to be deferred to a later meeting.

c) Review of Target Drug Format – In response to the Board's plan to consider building the target drug list around therapeutic/disease categories, Jude has circulated a list of drugs for the three major categories under consideration using the decision-making framework generated by the Board in: mental health, arthritis and asthma. He would like Dr Stahl, Dr Wong and Dr Jones respectively, to mark the drugs that they recommend to delete from future consideration within their topic to help reduce the lists to a more manageable size. Responding to questions about the design of the table, Jude noted that these lists are comprised of ALL drugs within a therapeutic category. Those drugs with no dollar value attached are drugs in which no money was spent. Additionally, the number of severity level one drug-drug interactions is the number of other drugs that each drug on this list has a severity level one drug interaction with. Severity level one is the most severe drug-drug interaction and the only one we alert on.

Dr Schell requested that following the first reduction of the drug list, we attach the specific drug-drug interactions for each remaining drug. Jude responded that this is labor intensive and it is preferable to wait until a final version of the list is prepared before performing this work. Dr Jones noted that the asthma list is not comprehensive for medications in asthma; specifically some of the inhaled steroids are missing. Vic responded that the inhaled steroids are actually listed under hormones and a more thorough search will identify them. Kevin recommended sending the list out prior to the meeting to insure we have a more finalized list for the meeting.

DUR/DISEASE MANAGEMENT

AWARE - the antibiotic over-utilization project led by the CMA Foundation for Community Health and attended by Janeen McBride has completed a compendium of antibiotic treatments for upper respiratory tract infections which is fully referenced and is currently planning pre and post measurement of antibiotic use in California. This measurement will include data from Medi-Cal, HMOs and possibly managed care. It will be referenced to HEDIS standards (a contract has been signed with NCQA on behalf of all participants by AWARE) and be used as a springboard for interventions as well as measurement of outcomes. Medi-Cal DUR is closely involved, providing data and expertise with the intent of helping shape a statewide program that will substantially benefit the Medi-Cal recipients as well as provide substantial cost containment. Additionally the statewide communication and participation network developed by this program could be a tremendous asset in future cooperative effort. Finally, it is a unique process to pool health care data across many groups. Janeen noted that February 28 is the steering committee meeting and awards dinner and their speaker's bureau is being expanded.

Atypical Education Project - Dr Stahl summarized by noting that the project is ready to demonstrate that the interventions work in a targeted way that documents outcomes. We are trying to figure out a cohort of physicians and may need to obtain an exemption from CHPS/IRB. We are also trying to move closer to guidelines without making them mandatory but built on a consensus. Virginia is the most recent state to contact us with interest in this project. Jude added that the Board packet contained a printout of a PowerPoint presentation illustrating the algorithm or decision guideline in selecting antipsychotics to treat schizophrenia. He included this both to share the actual progress with the Board and to suggest that this kind of preferential decision-making tool may be developed by all the projects. Since a guideline or algorithm of this nature can be

controversial, it is important we begin to discuss this process now, as the Board eventually may be voting on the use of guidelines.

Dr Stahl further noted that we tried to develop the program based on evidence and cost; trying to identify and reduce the use of high cost, low evidence options. How this is ultimately designed can be as political as it is scientific. He noted that the International Psychiatric Association has expressed interest in this algorithm for worldwide use of atypical antipsychotics. Additionally there was a review of polypharmacy by the Harvard Group (Don, Goff and Freundlich) that asked Dr Stahl to write an editorial which he titled "Antipsychotic Polypharmacy: Evidence Based or Eminence based?" This was published in *Acta Scandinavia*. These activities all point to the fact that people are looking for leadership from us and want us to assist them in evidence and cost-based guidelines. Once we have some sort of guideline, the final stage will be to move this out into general use and determine if there is a favorable impact on cost and quality of care.

Jude added that he and Vic are writing an article for the *Journal of Disease Management and Health Outcomes*. He thanked Trina Clark from Eli Lilly's Outcomes division for her abundant support, which has made the development of this article a great deal easier.

Arthritis Project – Dr Wong distributed two handouts for reference (Attachment 3 and 4) which represents a revision of the earlier program in consideration of the fact that many of the patients to be considered in this project may not have even had contact with a rheumatologist and determining these patients' view of their care is important. He drew the Board's attention to a study using the 5 percent sample in studying the Medi-Cal population from a Virginia based group in the late 1980's, now very outdated. This illustrates that there is a need for a current evaluation of care. Additionally, he emphasized the multi-disciplinary team center approach including USC, VA, and Cedars-Sinai.

Asthma Project - Dr Jones noted that directing positive change by incentivizing care standards is the ideal approach. He went on to present an overview of the asthma project via a PowerPoint presentation.

Emerging projects – Diabetes and pain management are on the horizon. A key element in the emerging field of Disease Management is the focus on multiple chronic diseases in a beneficiary rather than the development of entire programs one disease at a time. This is important because health care recipients are increasingly afflicted with multiple chronic diseases, forcing a revision of how disease is managed. Examples might include diabetes in mental health and pain management in arthritis. Dr Stahl noted that the CME requirement for physicians includes a requirement for pain management hours. This mandatory CME might be a vehicle for the DUR Board to get involved and impact what is being communicated to the medical practitioners. We can get our view woven into the message at a state level.

Brief Reports – Vic Walker noted that an audit is on-going and the results should be available in the next couple of months. He also noted that he and Jude will be doing both a platform and poster presentation to the American Drug Utilization Review Society (ADURS) on February 8th in San Antonio.

On-Going Reports

Early Refill Alert – Jude reported that document 3b shows the history of alert activity. Dr Stahl noted that the list of alerts is presented somewhat in the order the drugs are prescribed. He asked if there are any significant deviations from this ordering, where a drug's rate of prescribing was not proportional to the early refill alerts set on it. He observed that the only real outlier is oxycodone. Jude responded that until our alerts are anchored in some sort of larger conceptual schema, such as therapeutic categories, deriving useful meaning will be very difficult. Even cost savings are hard to evaluate in an early refill alert because the alert is not intended to stop the drug from reaching the patient, only from being dispensed in an untimely manner. Dr Jones responded that evaluation of cost savings in this situation requires a longer period of observation. Following a subset of claims over a year period is a better way of getting to the savings. He went on to provide an example, asking what is the predictive value of an early refill or high dose alert for albuterol relative to controller or reliever ratio. Is somebody who is filling a lot of albuterol having a low controller use? If so, then it is poor quality care. On the other hand, are they filling controllers at the same rate and is this just a reflection of the physician writing controllers and relievers on the same script? He suggested a couple of simple analyses. Dr Wong supported this observation, noting that use of a more complete dataset allows analysis to yield more substantial conclusions.

High Dose – Jude noted we are currently testing the high dose alert for all drugs on the formulary file. He distributed a handout provided by Nandu Prabhakaran, the DUR Systems Analyst that illustrates volume of high dose alerts for the new drugs over a one month period of time. Our initial tests show there are a considerable number of drugs setting a high dose alert that are not currently on the target drug list. The way our system calculates daily dose is the divide the days supply by the quantity and then multiply by the strength of the dose. This daily dose is compared to the First DataBank's high dose limits on file. When the dose exceeds this limit, an alert is sent to the pharmacist. Based on this, Jude requests the Board to consider voting to turn on all formulary file drugs for high dose alert or to propose another action that would move the decision making on this topic forward. Additional discussion focused on how the high dose alert will combine with the early refill alert to encourage accuracy in the field of days supply and the basic usefulness of this alert in insuring patient safety. Dr Wong observed that focusing only on one-time high dose alerts does not accurately capture those instances where a patient might have a long history of high dose alerts. Starting criteria would be two consecutive high dose alerts for a patient and then pull all claims for these patients to see what the trend is with this group. To provide the Board with a closer view of the activity of this alert, Jude will bring a breakout of the high dose alert activity to the May meeting**.** Vic requested that the FDB maximum dose accompany the report for each drug. Jude replied that this information is so stable and predictable over a long period of time that there may not be much gained by doing this. Richard Morita suggested that bringing back the maximum dose for the high alert volume drugs might be the best way to address this. Jude agreed to tailor the report in this manner showing the high dose alert number for each drug and an FDB value for maximum dose for the high volume drugs.

Meeting adjourned at 1 p.m.

OVERVIEW OF MEDS FILE HIPAA VARIABLE CHECKLIST

This table lists the three categories of data detailed in the HIPAA Privacy Rule regulations (45 CRF, Parts 160, 162 and 164) and the types of data allowed to be released in each of these categories.

There are no restrictions for releasing De-Identified data sets. Anyone may request and receive De-Identified data sets.

Limited and Confidential data sets may be disclosed only for the purposes of research, public health, or health care operations (please see the HIPAA regulations for details). Research is defined in the Privacy Rule as, “a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” The intent to disseminate findings outside of the requestor’s organization or industry is an essential condition for generalizability. Research should not be confused with healthcare operations such as quality assurance, marketing or other internal operations.

Release of data in Limited and Confidential data sets is restricted to the minimum necessary to achieve the stated goals of the requesting person or entity. This means that the requestor will need to justify their selection of variables, time periods, etc.

Release of Limited data sets will require a Data Use Agreement between the requester and MCSS. Release of Confidential data sets will require approval of the Department of Health Services' Committee for The Protection of Human Subjects, in addition to a Data Use Agreement.

MEDS File HIPAA Variable Checklist
Based On The 1025 Byte MEDS MEF

Variable*	Available For Use In De-Identified Data Sets (Safe Harbor Method**)	Available For Use In Limited Data Sets	Available For Use In Confidential Data Sets
1. Social Security Number			X
2. HIC Number			X
3. County Case Number			X
4. Date of Birth	Year or age only, but only for individuals less than 90 years of age.	Complete date is allowed for all individuals.	Complete date is allowed for all individuals.
5. Gender	X	X	X
6. Ethnicity	X	X	X
7. Language	X	X	X
8. SSAN VER CD	X	X	X
9. Redetermination Month	X	X	X
10. Case Name			X
11. Beneficiary Name			X
12. Beneficiary Address			X
13. Beneficiary City		X	X
14. Beneficiary State	X	X	X
15. Beneficiary Zip Code	First three digits are allowed, but only if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people. For all such geographic units containing less than 20,000 people the Zip Code must be zero filled or blank.	Complete Zip Code is allowed.	Complete Zip Code is allowed.
16. County Medi-Cal Worker (Medical District)			X
17. County Medi-Cal Worker (Medi-Cal Eligibilty Worker)			X
18. County Code		X	X
19. Aid Code	X	X	X
20. Eligibility Status	X	X	X
21. Other Coverage Code	X	X	X
22. Share of Cost	X	X	X
23. PHP Code	X	X	X

24. PHP Status	X	X	X
25. Medicare Status	X	X	X
26. Surs Code	X	X	X
27. Special County 1 Code		X	X
28. Special County 1 Aid Code	X	X	X
29. Special 1 Eligible Status	X	X	X
30. Special County 2 Code		X	X
31. Special County 2 Aid Code	X	X	X
32. Special 2 Eligible Status	X	X	X
33. Special Obligation	X	X	X

* Does not include Food Stamps variables, which we never give out.

** A Statistically de-indentified data set (e.g. a summarized data set) may have variables not allowed in a data set de-identified by the Safe Harbor Method.